EXHIBIT P

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August 1, 2023

By Email

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Re: *Arbutus Biopharma Corporation et al. v. Moderna, Inc. et al.*, C.A. No. 22-252-MSG (D. Del.) – **Moderna's RFP Responses and Objections**

Counsel:

We write in response to your May 11, 2023 letter. As stated in prior correspondence, given that your March 3, 2023 letter asked for a meet-and-confer regarding the issues raised therein—a request that was echoed in your March 6, 2023 email—and the parties have spent a considerable amount of time meeting and conferring on March 22, March 29, April 3, April 4, April 7, April 11, and April 12, 2023,[1] *see* May 11, 2023 Cash letter at 1, we trust that any issues that remained open from your perspective have been raised in your May 11, 2023 letter.

1. **Moderna's Production of Regulatory Documents**

As Plaintiffs are aware, Moderna has already produced well over 14,000 documents comprising over 450,000 pages, the majority of which are Moderna's regulatory documents submitted as part of its EUA, IND, and/or BLA submissions. Plaintiffs' statement that "Plaintiffs have repeatedly asked Moderna to produce its BLA and core technical documents, to no avail," is plainly inaccurate. A previously stated, Moderna's February 10, 2023 production of 40,000+

[1] We note that the first few meet-and-confers identified in Plaintiffs' letter were spent discussing Plaintiffs' deficient responses, not Plaintiffs' March 3, 2023 letter.

pages of technical specifications for Moderna's COVID-19 vaccine met and exceeded the requirement to produce Core Technical Documents "sufficient to show how the accused product(s) work(s)." D.I. 72 at ¶6(a). *See* April 25, 2023 McLennan letter. To the extent Plaintiffs are alleging that a deadline by which Moderna must produce the entirety of its regulatory submissions has passed, Plaintiffs are mistaken. Just as Plaintiffs' have allegedly been "repeatedly ask[ing] Moderna to produce its BLA and core technical documents" "for months," Moderna has been repeatedly asking Plaintiffs for documents responsive to Moderna's December 20, 2022 RFPs, including, for example, Plaintiffs' conception and reduction to practice documents. Regardless, we can confirm that Moderna has substantially completed production of the agreed-upon portions of the BLA, IND, and EUA. The parties are still months away from substantial completion of document production and our investigation is ongoing. We will timely produce any additional documents we locate, including new submissions.

With respect to your reference to Plaintiffs' correspondence regarding Moderna's confidentiality designations, we produced an overlay of the initial regulatory productions last month, resolving this issue.

2. **Moderna's General Objections to Plaintiffs' Requests**

(a) Third Parties

Moderna's Objection 3 to Plaintiffs' First Set of RFPs relates to Plaintiffs' definition of "You," "Your," and "Defendants" to the extent the terms include entities that are third parties and/or that Moderna does not control. Moderna's Objection 7 to Plaintiffs' First Set of RFPs relates to the production of documents and things subject to confidentiality obligations owed to third parties that prohibit or restrict their disclosure by Moderna.

Plaintiffs mischaracterize the parties' discussion during the meet-and-confer in stating that instead of providing a response to Plaintiffs' inquiries "Moderna pivoted to its demand that Plaintiffs agree to produce third-party documents, including documents subject to obligations of confidentiality to third-parties." In fact, Moderna explained that documents containing third party information could either be (1) in the possession of Moderna or (2) in the possession of third parties. As to the set of documents in category (1), as Plaintiffs themselves pointed out, Moderna has already produced a number of third-party documents, and we further assured you that we will not withhold documents in Moderna's possession, custody, or control on the basis of those documents being authored by a third party (putting aside any notice requirements or other obligations Moderna may have to said third parties). As to documents in category (2), as we made clear during the parties' meet-and-confer, it is premature to have the conversation about production of documents that are in the possession, custody, or control of third parties. Rather, as we stressed on the meet-and-confer, to the extent Plaintiffs believe material is missing from

Moderna's productions, we are willing to work with Plaintiffs to address your concerns. To that end, we are investigating what entities keep batch records, certificates of analysis, and "technology transfer" documents and will provide a response in due course.

Further, we are surprised that Plaintiffs are unwilling to agree to reciprocal discovery, as during the meet-and-confer Plaintiffs did not raise objections to our suggestions that the parties come to agreement on mutual scope. Moderna's common-sense suggestion for mutuality is grounded in Rule 26 and is based on proportionality and relevance. For example, if Plaintiffs contend that certain parts of the BLA are relevant, those same sections of Plaintiffs' regulatory filings are relevant as they would be necessary for us to assess what methods Plaintiffs are telling the FDA are accurate for the determination of, *inter alia*, lipid content.

Additionally, to the extent Plaintiffs contend that extensive searches and voluminous discovery from Moderna is "proportional to the needs of the case," that necessarily is applicable to Plaintiffs' discovery obligations considering the Rule 26(b) factors, particularly "2) the amount in controversy;" and the "the importance of the issues at stake in the action" which are the same for the parties.

Plaintiffs' continual practice of asking for more discovery from Moderna than Plaintiffs themselves are willing to provide is disappointing. If Plaintiffs are unwilling to provide certain discovery, they should not expect the same from Moderna.

(b) Public Documents

We understand that the parties have mutually agreed not to withhold responsive documents in their respective possession, custody, or control on the basis that the documents are otherwise publicly available. *See* March 29, 2023 McLennan letter at 7 ("You agreed that Plaintiffs would not withhold documents on the basis of them being publicly available and would collect such documents from the indicated repositories."). Thank you for confirming the same in your July 5 correspondence.

(c) Government redactions

At the time of your letter, Moderna had already produced the -0100 and -0017 Contracts without redactions. Further, as we made clear during the parties' meet-and-confers, to the extent Moderna needs to make redactions at the direction of the USG to comply with any applicable laws, including redactions for national security or privacy, we will do so. Though at present, we are not aware of any need to do so, we will inform Plaintiffs should that change at any point during discovery. Moderna's position is consistent with the ESI order, which allows the parties

to redact "patient Personal Identifiable Information, or other information to comply with applicable laws." We consider this issue to be fully resolved.

(d) Common interest privilege

Moderna has already indicated during the parties' meet-and-confers that these discussions are premature and at present, Moderna is not withholding documents on the basis of common interest privilege. To the extent Moderna withholds communications with the U.S. government on the basis of any form of privilege, they will be identified in our privilege log as such (if required to be logged based on the ESI order). At this time, nothing further is required from Moderna.

We understand from the parties' meet-and-confer that at least counsel for Arbutus was not prepared to discuss their position on disclosing entities with which it claims to have a common interest privilege.

(e) Documents sufficient to show

It is a well-known and common practice to limit responses to document requests to "documents sufficient to show." In fact, Plaintiffs themselves used the phrase to limit at least two of their requests, for example, seeking "Documents sufficient to show the time it took to develop the Accused Product." (Plaintiffs' Request 7). Moreover, Plaintiffs responded to dozens of Moderna's RFPs by agreeing to produce the "Contention Documents" which are defined as documents that ***Plaintiffs intend*** to rely upon, which is even more limited and, unlike Moderna's agreement to provide documents "sufficient to show," is entirely self-serving. If you contend Moderna's approach is improper, please explain how Plaintiffs' approach is any better.

Interestingly, Plaintiffs now identify Moderna's response to Request 7 as one example where "Moderna has deployed this limitation in its responses," conveniently neglecting to mention that documents "sufficient to show" is precisely what Plaintiffs sought. Regardless, as shown by the examples below, without applying any limitations, Plaintiffs' requests are unreasonably broad and collection and production of all documents responsive to such requests would go far beyond Moderna's discovery obligations, to the extent it would even be possible. It is not Moderna's obligation to either engage in an unreasonable collection of vast amounts of irrelevant materials or to rewrite Plaintiffs' Requests. To the extent Plaintiffs are not satisfied with Moderna's responses and believe there are categories of relevant documents that do not fall within the scope of the documents Moderna agreed to produce, as discussed with respect to specific Requests below, Moderna is willing to consider such requests.

For example, Plaintiffs' Request 5 seeks "[a]ll documents related to the manufacture of the Accused Product." *See also* Request 16 ("All documents related to the manufacturing process for the Accused Product, including but not limited to the manufacturing process for the LNPs in the Accused Product."). Without imposing any limitations, this Request would encompass documents far beyond anything relevant to this litigation—including all part orders for machines used during manufacturing, documents relating to maintenance of manufacturing facilities, testing of glass vials used to package the drug product, and other types of information wholly divorced from the lipid formulation of Moderna's COVID-19 vaccine—imposing an undue burden on Moderna. Moderna has already identified on the meet-and-confers at least its regulatory files disclose the entire manufacturing process for its COVID-19 vaccine. Yet, as discussed below, Plaintiffs insinuated that they do not believe that Moderna follows the manufacturing process it has presented to, and that has been approved by, the FDA. Plaintiffs offered no support for their allegations and such baseless accusations are not well-taken. Moderna will not engage in an exercise of producing a host of documents with little to no relevance to this litigation to enable Plaintiffs' fishing expedition.

Similarly, Plaintiffs' Request 12 seeks "[a]ll documents related to the formulation of the Accused Product." Paradoxically, Plaintiffs seem to have no problem asking Moderna for all documents "related to" a particular issue, yet in their own Objections and Responses take issue with Requests seeking documents "concerning" a particular issue.[2] February 2, 2023 Plaintiffs' Objections and Responses at 5. Please explain your understanding of this distinction. Regardless, Moderna has agreed to produce "non-privileged documents sufficient to show the formulation of Moderna's COVID-19 Vaccine identified after a reasonable and proportionate search." At the very least, Moderna's BLA and other regulatory submissions unambiguously lay out the formulation(s) of Moderna's COVID-19 vaccine. Plaintiffs have not explained what more they need.

To add to Plaintiffs' improperly broad requests, Plaintiffs were also wholly unwilling to cooperate with Moderna on trying to find workable compromises. For example, with respect to Plaintiffs' Request No. 6 ("All documents related to Operation Warp Speed."), Moderna attempted to understand what specifically Plaintiffs are seeking because, as discussed in further detail below, Operation Warp Speed was a broad government initiative and this request would capture a host of irrelevant material that has nothing to do with the aspects of the Accused

[2] We also note that Plaintiffs stated in their Responses and Objections that "Plaintiffs will consider as responsive to any Request that seeks documents or things 'concerning' or 'relating to' (or similar language) a designated subject only those documents or things that discuss the subject on their face." Moderna will then apply the same understanding in the course of its own collection and review.

Product that could have any relevance to the Asserted claims or to the claims and defenses of the parties, including the design and operation of clinical trials and supply chain logistics of completely irrelevant materials like glass vials. However, despite Moderna's attempts at compromise, Plaintiffs obstinately refused to narrow the scope.

Regardless of the foregoing, we can confirm that Moderna will not withhold a document on the basis of it containing duplicative information—even if not wholly duplicative—of another document.[3] However, Moderna also will not search for "all" documents as Requested by Plaintiffs, nor will Moderna expend the time and expense of collecting, reviewing, and producing a host of cumulative materials. To echo Plaintiffs, "[s]uch demands are unduly burdensome and overly broad, and they seek documents that are not relevant to the claim or defense of any party nor proportional to the needs of the case (in accordance with Fed. R. Civ. P. 26(b)(1))." As such, Moderna does not believe the parties are at an impasse on this issue.

(f) Products not accused of infringement and intermediate/non-final products

As stated during the meet-and-confer, Moderna will produce documents relevant to the earlier formulations of Moderna's COVID-19 vaccine, namely the formulations identified in Moderna's Response to Interrogatory No. 7. While Moderna will not withhold documents on the basis of those documents relating to "intermediate and/or non-final products" of its COVID-19 vaccine, Moderna maintains that such documents are not relevant to any claim or defense in this litigation. Despite repeated questions on the issue during the parties' meet-and-confers, Plaintiffs have failed to provide a cogent explanation as to why "intermediate and/or non-final products" are relevant to the claims asserted by Plaintiffs in this action, which recite properties of a finished product comprising an encapsulated nucleic acid. Plaintiffs accuse Moderna's COVID-19 Vaccine—a finished drug product—of infringement. *See, e.g.,* Compl. at ¶ 8 (defining the Accused Product); ¶ 97 (referring to alleged administration of the Accused Product to patients). Plaintiffs have repeatedly failed, both during the meet-and-confers and in their June 22 correspondence, to provide an explanation of the relevance of any intermediates given Plaintiffs accuse the final product of infringement in their Complaint.

(g) Government sales

While Moderna is not withholding documents on the basis of those documents relating to sales to the U.S. Government, Moderna preserves Objection 20, as put forth in its February 2, 2023 Objections and Responses.

[3] Subject to any agreement about thread de-duplication in the parties' ongoing discussions.

(h) "Foreign" batches

Your May 11, 2023 letter once again misrepresents the parties' discussions during the meet-and-confers. Contrary to your statement that "Moderna agreed that in order for the Court (or even Plaintiffs) to assess Moderna's claims concerning allegedly 'foreign' infringing activity, it would require Moderna to produce information regarding that foreign activity, including for instance, with respect to allegedly 'foreign' batches or doses of the Accused Product," we had merely pointed out that Plaintiffs have already served Interrogatory 11, which may provide all of the information Plaintiffs want and/or need on this front. Moderna did not agree that Moderna is broadly required to "produce information regarding that foreign activity." We continue to investigate what information is available with respect to Plaintiffs' Interrogatory No. 11 and will supplement Moderna's response in due course. If you have support indicating that batches made outside the U.S. and never imported into the U.S. can constitute infringement of a U.S. patent, we remain willing to consider it.

(i) Safe Harbor

As with Objection 20, we confirmed on the meet-and-confer that Moderna is not withholding documents on the basis of 35 U.S.C. § 271(e), but we nonetheless preserve the objection if Plaintiffs seek an unreasonable and disproportionate amount of discovery into batches that are clearly for FDA approval.

3. **Plaintiffs' General Inquiries**

(a) Search Strategy

We understand any purported issues have been resolved by Moderna's disclosure of ESI search terms.

(b) Internal communications and documents

As stated above, we maintain that Moderna's common-sense suggestion for mutuality is grounded in Rule 26 based on proportionality and relevance. It is also unclear how Plaintiffs are distinguishing Moderna's "technical document production" from any other type of production Moderna makes in this case. Regardless, we have addressed Plaintiffs concerns with respect to specific RFPs below.

(c) Analytical tests

First, Plaintiffs are surely aware of the claims that have been asserted in this litigation and what analytical testing would and would not be relevant to any elements of the claims Plaintiffs

RFP 53: We understand that Plaintiffs are only seeking indemnification agreements and warranties for infringement of intellectual property. We are looking into your Request and will respond in due course.

RFPs 54, 55: In its February 2, 2023 Responses and Objections, Moderna offered to meet and confer with Plaintiffs regarding these Requests, which the parties have now done. Again, your characterization of the parties' meet-and-confer is inaccurate, at least with respect to your statement that "Moderna did not dispute the relevance of these documents with respect to at least Moderna's willful infringement, but instead sought Plaintiffs' reciprocal agreement to produce documents related to foreign patent office proceedings." May 11, 2023 Cash letter at 11. In fact, we asked Plaintiffs for your basis for arguing that any related applications or foreign applications are relevant to willfulness. As noted above, Plaintiffs failed to provide any support on the meet-and-confer, nor has any support been identified in Plaintiffs' May 11 letter. Please provide any support you have for your position for our consideration.

RFPs 57, 58, and 59: Please explain, with case law support, how foreign licenses would be relevant to a damages analysis of U.S. patents. Moderna will not embark on a burdensome goose chase across the dozens of countries in which Moderna sells its COVID-19 vaccine based on conclusory assertions of relevance.

We note that on the meet-and-confer Plaintiffs indicated that they were still investigating whether Plaintiffs will produce documents relating to foreign licenses. Since then, Plaintiffs have only agreed to produce documents relating to licenses concerning the Patents-in-Suit, which are U.S. patents.

RFP 60: In its February 2, 2023 Responses and Objections, Moderna offered to meet-and-confer, which the parties have now done. Contrary to your May 11 letter, documents relating to "foreign" agreements was not the only issue we raised with your Request on the parties' meet-and-confers. In fact, the parties had a discussion as to what exactly Plaintiffs are after with this Request. For example, when we asked Plaintiffs if they would consider every FedEx slip to be responsive to this Request as an agreement or contract to distribute Moderna's COVID-19 vaccine, Plaintiffs agreed that they would not. As we were not able to get a clear answer from Plaintiffs' as to what exactly Plaintiffs are seeking, please explain in detail what documents are covered by Plaintiffs' Request as it is now apparent to all parties that it is not truly all "written agreement[s], contract[s], or license[s] concerning the development, manufacture, sale, or distribution of the Accused Product." May 11 Cash letter at 11.

RFPs 61, 62, and 63: Moderna has produced the -0017 Contract. We are considering compromise proposals for these Requests and will provide any such proposals in due course.

RFPs 64 and 69: during the parties' meet-and-confer, we asked Plaintiffs to explain the relevance of the documents they seek with these Requests. Plaintiffs asserted that discussions relating to the price of Moderna's COVID-19 vaccine are relevant to damages. Though we expressed that we do not understand how internal documents and communications are relevant when Moderna had agreed to, and now has produced, the -0100 and -0017 contracts, we agreed to consider Plaintiffs' RFP 64. Moderna also noted, and Plaintiffs did not dispute, that the documents Plaintiffs had identified as relevant and responsive to Request 69 would be subsumed within RFP 64, therefore Moderna will not separately search for documents responsive to RFP 69.

Moderna is willing to consider producing non-privileged communications regarding the -0100 and -0017 Contracts, specifically the negotiations of those agreements, discussions of their terms, analysis of the benefit to the U.S. Government stemming from those agreements, and/or discussions of patent indemnity. If Plaintiffs do not agree to this proposal, please provide your own proposal and explain why Moderna's offer is insufficient. As explained on the meet-and-confer and stated in Moderna's February 2 Responses and Objections, Plaintiffs request for "[a]ll documents related to any negotiations between Defendants and any third party" is far too broad, would sweep in a host of agreements that have no relation to the issues in this litigation, and the resulting burden to Moderna would be far disproportionate to the needs of the case.

RFPs 70 and 71: With respect to Request 70, Moderna has already agreed to and substantially produced BLA No. 125752, IND 19745, and EUA No. 27073. With respect to any foreign submissions, the parties discussed, and Plaintiffs indicated they would be willing to at least consider, that the production of a representative set of submissions or portions thereof, may satisfy Plaintiffs' request. We are considering this proposed compromise and investigating how many versions of foreign submissions exist and will provide an update in due course. With Respect to RFP 71, we maintain that if Plaintiffs continue to demand internal communications from Moderna, Plaintiffs should be prepared to produce the same. Please confirm you will do so and we will consider your Request, though we note that Plaintiffs have not identified, either in their letter or on the parties' meet-and-confers, why Plaintiffs need internal communications relating to communications with the FDA when Moderna has already agreed to produce the FDA communications themselves.

RFP 77: The only relevance argument Plaintiffs offered on the meet-and-confer was for the assessment of projected sales as of the date of the hypothetical negotiation. However, as noted on the meet-and-confer, we are unable to consider this position due to Plaintiffs' failure to respond to our Interrogatory on the same. Your statement that "Plaintiffs reiterate the relevance of historical forecasts" without providing any actual position on the relevance of such documents adds nothing. Please supplement your Interrogatory response and we will investigate whether it

would be feasible to produce "historical forecasts" Plaintiffs allege to be relevant for the date of alleged hypothetical negotiation. We await Plaintiffs' response.

RFPs 80, 81, and 83: In its February 2, 2023 Responses and Objections, Moderna offered to meet and confer with Plaintiffs regarding these Requests, which the parties have now done. With respect to Request 80, we informed you on the meet-and-confer that we are investigating what would be feasible in light of what information is kept in the ordinary course of business. Our investigation is ongoing and we will provide a response in due course.

We also understand from the parties' meet-and-confers that Plaintiffs are not seeking lab supply orders, for example. Given that such orders could be construed as "a commercial agreement Defendants have made with any third party relating to the Accused Product," Moderna does not have sufficient guidance from Plaintiffs as to what falls within, and what falls outside, Request 81. Please provide a more tailored request that is focused on the documents Plaintiffs actually seek pursuant to Request 81 so that Moderna may consider it.

With respect to Request 83, we fail to see what documents Plaintiffs seek that would not be responsive to and produced in relation to other Requests, including those relating to the -0100 Contract. To the extent Plaintiffs believe there is some non-duplicative scope they are entitled to in light of the discussions on the meet-and-confers and those above, please identify such documents so we may consider Plaintiffs' request.

RFP 84: We understand that Plaintiffs' Request 84 seeks studies, preprints, and publications relating to Moderna's research and development of its COVID-19 vaccine and any internal documents and communications relating to the same. At the outset, we note that any publications would already be available to Plaintiffs. While Moderna will not withhold documents on this basis, Moderna also will not specifically search for such publicly available documents. As noted above, we understand that Plaintiffs have taken the same position.

With respect to communications, on the meet-and-confer we specifically asked Plaintiffs to identify the relevance of any internal communications relating to such publications. The only basis Plaintiffs was able to identify related to the Corbett et al. publication identified above. Moderna has already agreed to produce non-privileged communications referring to Corbett et al. Plaintiffs have not identified a basis for relevance of any additional documents responsive to this Request, so we trust this resolves Plaintiffs' demands with respect to this Request.

RFPs 85, 86, and 87: With respect to both Requests 85 and 86, in its February 2, 2023 Responses and Objections, Moderna offered to meet and confer with Plaintiffs regarding these Requests, which the parties have now done. With respect to RFPs 85 and 86, Moderna understands that Plaintiffs contend that Moderna's own patents are relevant because Moderna's

COVID-19 vaccine is a product of Moderna's own inventions and therefore those patents are relevant to this litigation. Moderna disagrees with Plaintiffs' position, but in the spirit of compromise, will produce copies of its U.S. patents covering its COVID-19 vaccine.

With respect to Request 87, we maintain that to the extent Plaintiffs seek discovery of communications, Plaintiffs should be prepared to produce the same. We will consider your Request once the parties have reached agreement on the scope of discovery relating to communications.

RFPs 95 and 96: Once again Plaintiffs mischaracterize the parties' meet-and-confers. Contrary to your allegation that "[n]or did Moderna on our meet-and-confers explain any burden associated with simply producing the requested documents," we specifically raised the burden to Moderna, explaining that it would be burdensome for us to have to confirm, for each document that had been produced in another lawsuit, whether that document had been collected, reviewed, and produced in this case. In fact, it was Plaintiffs who could not identify any basis for relevance of these documents other than pointing out that the products at issue are the same in both cases. However, different patents are at issue in the two cases. Your May 11 letter further states that "the patent asserted in *Alnylam* is related to the LNP technology that is at issue here." May 11 Cash letter at 13. That is unsurprising considering the same products are at issue, but fails to address the fact that there is also a significant amount of non-overlapping subject matter.

Nevertheless, in the spirit of compromise, Moderna has put forth a proposal in its July 3, 2023 correspondence. We continue to await Plaintiffs' response and reserve all objections in the meantime.

RFPs 97 and 98: Moderna has addressed your arguments with respect to Plaintiffs' Interrogatories Nos. 6 and 11 in an earlier letter. As discussed on the parties' June 5 meet-and-confer, Moderna's investigation into Plaintiffs' ROG 11 is ongoing and we will provide the requested information, subject to Moderna's responses and objections, in due course.

Moderna reserves all objections.

Sincerely,

/s/Mark C. McLennan
Mark C. McLennan